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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,419	03/15/2004	John Lezdey	1434-19	1964

7590 03/08/2007

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EXAMINER	
BETTON, TIMOTHY E	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/801,419	LEZDEY ET AL.	
	Examiner	Art Unit	
	Timothy E. Betton	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *3 and 5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 6-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election in the reply filed on 29 January 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status of the Claims

Claims 1-12 are pending. Claims 3 and 5 are withdrawn. Claims 11 and 12 have been added.

Claim Rejections-- 35 USC§ 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, and 6-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the disclosed administration of a therapeutically effective amount of composition containing a cromolyn compound when inflammation is indicated or an acute inflammatory response has been detected, does not reasonably provide enablement for the prevention or complete inhibition of the formation of lesions following inflammation of affected epidermal region. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with

these claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The standard for determining whether the specification meets the enablement requirement is whether experimentation needed to practice the invention is undue or unreasonable. Accordingly, even though the foregoing statute does not use the term "undue experimentation", it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can perform the methods as claimed without undue experimentation. See MPEP § 2164.

As stated in MPEP 2164.01(a), " There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue."

In re Wands, set forth the following eight factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, 1ST paragraph:

1. The nature of the invention;
2. The state of the prior art;
3. The predictability or lack thereof in the art;
4. The amount of direction or guidance present;
5. The presence or absence of working examples;
6. The breadth of the claims;
7. The quantity of experimentation needed; and
8. The level of the skill in the art.

The nature of the invention

The invention is in the field of treatment directed toward a method of inhibiting skin lesions resulting from activation of proteinase activated receptor-2. The nature of

the invention is, therefore complex due to the intermolecular and physiological disclosure in regard to scope of invention.

The state of the prior art and the predictability or lack thereof in the art

There is no reasonable predictability even in view of the seemingly high level of skill in the art.

Through practicing of the instant invention, it is highly unlikely that the contemporary knowledge in the art would allow one of ordinary skill in the art to accept that the instantly claimed compounds or pharmaceutical compositions thereof are capable of predictably totally palliating, preventing, and inhibiting lesions from forming in an affected region of skin upon initial detection that inflammation is present on said region of skin.

The amount of direction or guidance present

The amount of direction or guidance present in instant specification and claim set is deficient in light of the nature of the alleged invention (method of inhibiting skin lesions). The disclosures of instant invention do not present sufficient direction or guidance within the instant specification in the way of determining or disclosing working models to suggest the therapeutic affect of application on epidermis to prevent lesions. Working models fail to discloses processes by which one of ordinary skill in the art may ascertain that the application of a formulation comprising cromolyn sodium resulted in marked inhibition and/or prevention of progression to skin lesions upon an affected region of epidermis (Lezdey et al. (PG PUB US 2001/0041684 A1, page 2, [0025]).

The breadth of the claims and quantity and the quantity of experimentation

The breadth of the claims is broad including variant factors, which would require continued exhaustive experimentation. The level of the skill in the art requires high expertise due to the nature of the invention.

Again, as stated in MPEP 2164.01(a), " There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue."

In instant claims 1 and 10, the term "inhibiting" and "prevention" in relation to the breadth of the claims fails in view of the specification, which discloses no sufficient working models to suggest that a cromolyn formulation could prevent associated disease states associated epidermal inflammation, eruptions, and lesion activity.

Claim Rejections- - 35 USC§112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "inhibiting" in instant claim 1 and the term "preventing" in instant claim 10 are relative terms, which render the respective claim(s) indefinite. The term

"inhibiting" and "preventing" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

One suggestion in regard to appropriate claim set language would be a modification to read: ex. A method for treating or administering said agent to a site of inflammation on skin to diminish the progression to skin lesions.

The term "inhibiting" and "preventing" relate to a consistent and defined magnitude of therapeutic effectiveness that has not been adequately disclosed or explained in the instant specification and/or instant claims.

Claim 8 recites the limitation "A method" which is dependent from instant claim, which initially discloses method. Therefore, instant claim 8 should read "*The* method [...]" instead of "*A* method [...]", thereby drawing dependence from instant claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections- 35 USC§103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4, and 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lezdey et al. (USPN 6,379,684 B1), in view of Costanzo (USPN 6,323,219 B1).

Lezdey et al. teach cosmetic compositions and methods comprising an effective amount of cromolyn compounds to provide a prophylactic or repairing effect (Abstract; column 1, lines 10-12, 22-25, 35-43; column 2, lines 60-65)[to the affected area of skin]. Further, Lezdey et al. teach the etiology of lesions particularly via radiation. The consequent administration of the cromolyn compound reduces the risk of cellular proliferation when applied in a suitable composition (column 3, line 6-9; column 4; lines 20-25; column 1, lines 63-68).

Costanzo teaches methods and compositions for treating inflammatory disorders and immunomediated inflammatory diseases. Additionally, Costanzo teaches particularly upon the mechanism of action of proteinase-activated receptor-2 (PAR-2) (column 2, line 19-39). Further, Costanzo teaches a practicing method of inhibiting tryptase via administration of the cromolyn compound (column 31, lines 61-67; columns 32-35).

Lezdey et al. and Costanzo do not identically disclose an invention drawn to a cromolyn compound administered to treat a site of inflammation prior to the formation of lesions.

However, it would be prima facie obvious to combine the methods and compositions of Lezdey et al. and Costanzo. One of ordinary skill in the pertinent art would at once recognize the motivation to combine the two references based on their obviousness over the claimed invention. Lezdey et al. and Costanzo are both drawn to the prophylactic and reparation of skin tissue in order to inhibit skin lesions. Both references teach the administration to the skin when inflammation is detected and the

prospect of skin lesions and various other epidermal eruptions are anticipated. A reasonable expectation of success in obviousness over claimed invention would be present if the methods and compositions of Lezdey et al. and Costanzo were both modified or simply incorporated together. The central issue of a method of inhibiting skin lesions is adequately identified in the incorporating of Lezdey et al. and Costanzo together.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB

Ardin H Marschel 3/4/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER